



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0721]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-0721 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue

Certifications--21 CFR Part 1, Subpart M

OMB Control Number 0910-0750--Extension

This information collection helps to implement FDA's Accredited Third-Party Certification Program (also referred to as the third-party food program), established and administered under section 808 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), and codified in 21 CFR part 1, Subpart M (21 CFR parts 1.600 through 1.725) of Agency regulations. The regulations communicate eligibility criteria, assessment standards, and establish procedures and requirements for participation. For more information visit our website at <https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program>.

Under the third-party food program, accreditation bodies (ABs) apply to FDA for recognition. Recognized ABs accredit third-party certification bodies (CBs) under the program, except in limited circumstances. The accredited CBs conduct food safety audits and issue food or facility certifications to eligible foreign entities. FDA uses certifications issued by accredited third-party auditors/CBs in deciding whether to admit certain imported food (both food for human and other animals) into the United States. Under the third-party program, FDA may grant recognition of an AB for up to 5 years from the date of recognition. Current third-party program AB participants are recognized for the duration from 2018 to 2023 and will need to submit renewal of recognition applications to continue their participation.

There are approximately 200,000 foreign food (both food for human and other animals) exporters who offer their food products for import into the United States. These foreign food exporters include approximately 130,000 food production facilities and approximately 71,000 farms. A proportion of these foreign food exporters may offer food subject to mandatory certification requirements under section 801(q)(3) of the FD&C Act (21 U.S.C. 381(q)(3)). In that case, to continue exporting food products into the United States, eligible entities must either obtain certification from a CB accredited under the third-party program, or obtain certification from a foreign government designated by FDA. We assume in any given year, 75 foreign food exporters will be subject to requirements in section 801(q) of the FD&C Act.

Participating in the third-party accreditation program helps reduce the number of redundant audits necessary to assess compliance with food safety requirements of the FD&C Act and applicable regulations. Required data elements are submitted using FDA’s Unified Registration Listing System (FURLS), an electronic portal (Forms FDA 3997 for ABs and 3997a for CBs) that enables respondents to complete data fields and provide information to FDA electronically. The AB and CB portals provide a standardized format for entering information, prompting respondents for input and facilitating FDA’s review of the submittal. Instructions may be accessed at <https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program>.

Respondents to the collection of information are eligible entities seeking audits, certification, and/or recertification by accredited CBs participating in the third-party program, and ABs and CBs seeking to comply with the recognition requirements. An eligible entity is a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit conducted by an accredited third-party CB.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Part 1, Subpart M	No. of Respondents	No. of Responses per Respondent ²	Total Annual Responses	Average Burden per Response ²	Total Hours
AB applications, renewals, notifications, revocations	25	11.36	284	3.18	903
CB certifications, regulatory audits and assessments, notifications	208	147.29	30,638	0.25 (15 minutes)	7,661
CB applications for direct accreditation & renewal	1	1	1	90	90
Total			30,923		8,654

¹ We estimate no capital costs or operating and maintenance costs for the information collection.

² Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper ²	Total Annual Records	Average Burden per Recordkeeping ²	Total Hours
AB documenting certification procedures; maintaining applicable records	25	426.56	10,664	0.25 (~15 minutes)	2,677

AB establishing and updating public list of CBs	25	1	25	52.8	1,320
CB documenting procedures for accreditation; maintaining applicable records (audits, certifications, serious risks)	208	112.72	23,446	0.35 (~20 minutes)	8,228
CB establishing & updating public list of eligible entities	208	1.31	273	44.19	12,064
Contract modification ²	7	9	63	2	126
Total			34,471		24,415

¹ We estimate no capital costs, or operating and maintenance costs for the information collection.

² Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours.

We include in our estimate reporting burden attributable to required submissions, including notifications, to FDA; and recordkeeping burden attributable to the time we assume necessary for searching data sources, and preparing and maintaining records described in the applicable regulations. We estimate that 25 ABs will accredit CBs who conduct food safety audits of foreign eligible entities that offer food for import to the United States. We also estimate the 208 accredited CBs will participate in the third-party program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA. Finally, we attribute nominal burden to recordkeeping attendant to contractual modifications that may be part of accreditation.

Based on a review of the information collection since last OMB approval, we have made only nominal adjustments to our burden estimate.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.